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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,528	11/27/2001	Sheng-Ping Zhong	S13.12-0124	8767
26161	7590	04/11/2005	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			SMITH, RUTH S	
			ART UNIT	PAPER NUMBER
			3737	

DATE MAILED: 04/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,528

Applicant(s)

ZHONG ET AL.

Examiner

Ruth S. Smith

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9,12-25,29-59,63-65,67 and 69-92 is/are pending in the application.
- 4a) Of the above claim(s) 29-55 and 71-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9,12-25,56-59,63-65,67,69,70 and 85-92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7,9,14-16,18-25,56-57,59,63-65,67,69,85-92 are rejected under 35 U.S.C. 102(e) as being anticipated by Schachter et al. The claims are directly readable on Schachter et al which disclose a medical device coated with a hydrophilic polymer and a plurality of paramagnetic ions/particles in order to enhance magnetic resonance visibility of the device. The coating procedure can involve dipping which would inherently provide coating both the inner and outer surfaces of any device such as a catheter which is known to include lumens. The paramagnetic ions/particles and hydrophilic material comprises the materials as set forth in the claims. The coating also includes a structural polymer as set forth in the claims. With respect to claims 2-4,18-20, it should be noted that page 2, paragraph 14 discloses the use of a paramagnetic metal salt, a paramagnetic metal chelate and paramagnetic metal complex. The claims are considered to be product by process claims and the manner in which the product is made fails to affect the patentability of the product.

Claims 1,3-7,9,14-16,19-25,56,59,63-65,67,69,85-92 are rejected under 35 U.S.C. 102(e) as being anticipated by Frayne et al. The claims are directly readable on Frayne et al which disclose a medical device coated with a hydrophilic polymer and a plurality of paramagnetic ions/particles in order to enhance magnetic resonance visibility of the device. The coating procedure can involve dipping which would inherently provide coating both the inner and outer surfaces of any device such as a catheter which is known to include lumens. The paramagnetic ions/particles and hydrophilic

material comprises the materials as set forth in the claims. The coating also includes a structural polymer as set forth in the claims. The claims are considered to be product by process claims and the manner in which the product is made fails to affect the patentability of the product.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2,18,22,23,57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frayne et al in view of Young et al. Frayne et al disclose a medical device coated with a hydrophilic polymer and a plurality of paramagnetic ions/particles in order to enhance magnetic resonance visibility of the device. The coating procedure can involve dipping which would inherently provide coating both the inner and outer surfaces of any device such as a catheter which is known to include lumens. Young et al disclose a medical device such as a catheter having paramagnetic particles incorporated therethrough in order to provide enhanced detectability when viewed by magnetic resonance imaging. The paramagnetic materials can comprise a paramagnetic cation

incorporated or encapsulated together with a proton-donating fluid in a carrier particle. The paramagnetic ion may be any metal ion displaying paramagnetic properties, typically being an element of atomic numbers 21-29, 42, 44, and 58-70. Exemplary transition metal cations include Gd^{+3} , V^{+4} , V^{+3} , Cu^{+2} , Ni^{+2} , Cr^{+3} , Co^{+3} , Co^{+2} , Cr^{+3} , Fe^{+3} , Fe^{+2} , and the like. The cations will normally be in the form of a salt, including sulfates, chlorides, acetates, nitrates, and the like, as counter ions. It would have been obvious to one skilled in the art to have modified Frayne et al such that it includes the paramagnetic materials disclosed by Young et al. Such a modification merely involves the substitution of one well known type of paramagnetic particles for use in MR detectability for another. Young et al further disclose that the particles may be dispersed uniformly throughout the catheter or may be dispersed in a preselected pattern such as a circumferential band or an axial band extending partially or wholly along the length of the tube. It would have been obvious to one skilled in the art to have modified Schachter et al such that the components are dispersed in either a striped or spiral pattern as shown by Young et al. The advantage of such is to enhance the visibility of the particles by placing them in a known pattern.

Claims 12,13,70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schachter et al in view of Frayne et al . Schachter et al disclose a medical device coated with a hydrophilic polymer and a plurality of paramagnetic ions/particles in order to enhance magnetic resonance visibility of the device. Frayne et al disclose an MR visible catheter having an antenna mounted therein to provide enhanced MR imaging in the area to be diagnosed (see page 4, lines 1-10). It would have been obvious to one skilled in the art to have modified Schachter et al such that it includes an antenna for detecting MR signals. The advantage of such is to enable enhanced MR imaging in a specific area to be diagnosed in the patient as is well known in the art.

Claims 12,13,70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frayne et al . Frayne et al disclose a medical device coated with a hydrophilic polymer and a plurality of paramagnetic ions/particles in order to enhance magnetic resonance

visibility of the device. The coating procedure can involve dipping which would inherently provide coating both the inner and outer surfaces of any device such as a catheter which is known to include lumens. Frayne et al disclose that it is known to enhance detectability of an MR catheter by having an antenna mounted therein (see page 4, lines 1-10). It would have been obvious to one skilled in the art to have modified Frayne et al such that it includes an antenna for detecting MR signals. The advantage of such is to enable enhanced MR imaging in a specific area to be diagnosed in the patient as is well known in the art.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schachter et al or Frayne et al in view of Hashimoto et al, or Rhoades et al or Pricone et al. Schachter et al disclose a medical device coated with a hydrophilic polymer and a plurality of paramagnetic ions/particles in order to enhance magnetic resonance visibility of the device. The coating procedure can involve dipping which would inherently provide coating both the inner and outer surfaces of any device such as a catheter which is known to include lumens. The paramagnetic ions/particles and hydrophilic material comprises the materials as set forth in the claims. The coating also includes a structural polymer as set forth in the claims. Frayne et al disclose a medical device coated with a hydrophilic polymer and a plurality of paramagnetic ions/particles in order to enhance magnetic resonance visibility of the device. The coating procedure can involve dipping which would inherently provide coating both the inner and outer surfaces of any device such as a catheter which is known to include lumens. The process of cross-linking material to enhance durability is old and well known as shown for example by Hashimoto et al, Rhoades et al and Pricone et al and therefore, it would have been obvious to one skilled in the art to have modified either Schachter et al or Frayne et al such that the hydrophilic polymer is cross-linked in that such is a well known expedient in the art.

Claims 22,23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schachter et al in view of Young et al. Schachter et al disclose a medical device

coated with a hydrophilic polymer and a plurality of paramagnetic ions/particles in order to enhance magnetic resonance visibility of the device. Young et al disclose a medical device such as a catheter having paramagnetic particles incorporated there through in order to provide enhanced detectability when viewed by magnetic resonance imaging. The particles may be dispersed uniformly throughout the catheter or may be dispersed in a preselected pattern such as a circumferential band or an axial band extending partially or wholly along the length of the tube. It would have been obvious to one skilled in the art to have modified Schachter et al such that the components are dispersed in either a striped or spiral pattern as shown by Young et al. The advantage of such is to enhance the visibility of the particles by placing them in a known pattern.

Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schachter et al or Frayne et al in view of Weber et al. Schachter et al disclose a medical device coated with a hydrophilic polymer and a plurality of paramagnetic ions/particles in order to enhance magnetic resonance visibility of the device. The coating procedure can involve dipping which would inherently provide coating both the inner and outer surfaces of any device such as a catheter which is known to include lumens. The paramagnetic ions/particles and hydrophilic material comprises the materials as set forth in the claims. The coating also includes a structural polymer as set forth in the claims. Frayne et al disclose a medical device coated with a hydrophilic polymer and a plurality of paramagnetic ions/particles in order to enhance magnetic resonance visibility of the device. The coating procedure can involve dipping which would inherently provide coating both the inner and outer surfaces of any device such as a catheter which is known to include lumens. Frayne et al and Schachter et al fail to specifically disclose the use of dysprosium oxide. Weber et al disclose a catheter including paramagnetic materials to enable it to be visualized using MRI. The paramagnetic materials can comprise dysprosium oxide. It would have been obvious to one skilled in the art to have modified Frayne et al or Schachter et al such that the

paramagnetic particles are dysprosium oxide. Such a modification merely involves the substitution of one well known type of paramagnetic particle for another.

Response to Arguments

Applicant's arguments filed March 14, 2005 have been fully considered but they are not persuasive. The claims are considered to be product by process claims and the manner in which the product is made fails to affect the patentability of the product. The patentability of a product does not depend on the method of production and the limitations in the claims regarding, for example, co-extrusion, is considered to be directed to the process of making.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3737

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Ruth S. Smith', with a stylized, cursive script.

Ruth S. Smith
Primary Examiner
Art Unit 3737

RSS